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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/272,835	03/19/1999	FREDERIC J. DE SAUVAGE	P1268R1	6145

7590

07/24/2002

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EXAMINER

HAYES, ROBERT CLINTON

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 07/24/2002

24

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/272,835

Applicant(s)

De Sauvage et al

Examiner

Robert C. Hayes, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5/1/01 and 5/2/02
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 66-85 is/are pending in the application.
- 4a) Of the above, claim(s) 66-71, 74-76, 78-80, and 82-84 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 72, 73, 77, 81, and 85 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 66-85 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 13 6) ☐ Other:

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DETAILED ACTION

Response to Amendment

1. Newly submitted claims 66-71, 74-76, 78-80 & 82-84 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The originally elected invention was related to a polynucleotide encoding the *human* GFR α 3 of SEQ ID NO:15, in which those portions of SEQ ID NOs: 17 & 20 that were previously claimed were examined because these sequences included either the same *human* GFR α 3 sequence, or an alternatively spliced variant of the *human* GFR α 3 sequence. In contrast, a polynucleotide encoding the *murine* GFR α 3 is distinct because it encodes a unique protein, as illustrated by its unique amino acid sequence, which requires a different undue search burden. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits.

Accordingly, claims 66-71, 74-76, 78-80 & 82-84 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

This application contains claims 66-71, 74-76, 78-80 & 82-84 drawn to an invention nonelected with traverse in Paper No. 9. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

2. The amendments filed 05/01/01, 8/7/01, 1/30/02 and 4/19/02 have been entered.

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3. The rejection of claims 1-15 under 35 U.S.C. 102(a) as being anticipated by Sanicola-Nadel et al. (WO97/44356; IDS REF #6), is withdrawn due to the cancellation of these claims, and because the currently elected claims are not 100% identical to the *human* SEQ ID NO:17, but a splice variant thereof, which Sanicola-Nadel et al. do not specifically teach (i.e., as it relates to claims 72-73).

4. Applicant's arguments filed 05/01/01 have been fully considered but they are not persuasive.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 72-73, 77, 81 & 85 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and/or substantial asserted utility or a well established utility, for the reasons made of record for cancelled claims 1-15, and as follows.

Applicants argue on page 8 of the response that "[a]lthough at the time of filing the present application, the native ligand of GFR α 3 was unknown, the application is not without disclosure concerning the function of GFR α 3", refers to data related to *murine* GFR α 3 published 17 months after the claimed priority date of the instant application, as well as Figure 8 and page 29 of the specification. However, the disclosure on page 29 merely invites others to

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experiment to discover what specific disease states may be treated from a laundry list “including, but not limited to...”, in which the full passage on lines 2-8 further actually states that “GFR α 3 or its agonist or antagonists can be used to treat conditions...”. In other words, without knowing the native ligand of GFR α 3, one of ordinary skill in the art would not reasonably know what specific “conditions” could reasonably be “treat[ed]”, nor reasonably know what “agonists or antagonists” putatively exist, if later discovered. Accordingly, the court in *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, 1117, makes clear that “applicant must convey with reasonable clarity to those skilled in the art that, *as of the filing date sought*, he or she was in possession of *the claimed invention* [emphasis added]”, which the current specification does not adequately describe.

Therefore, because no known biological activity is described within the instant specification nor specifically associated with any nucleic acid that encodes the polypeptides of SEQ ID NOs:17, because the specification merely discloses on page 55 that the human “GFR α 3 does not bind any of these [GDNF family member] molecules (Figure 9C)”, and that “GFR α 3 is thus an orphan receptor”, the claimed polynucleotides have no specific nor substantial utility because further experimentation is necessary at the time of filing the instant invention to attribute a function and “real world” utility to the claimed nucleic acid molecules.

Applicant is again directed toward the Revised Interim Utility Guidelines, Federal Register, Vol.64, No.244, pages 71427-71440, Tuesday December 21, 1999.

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7. Claims 72-73, 77, 81 & 85 are also rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention is not supported by either a specific and/or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention, for the reasons made of record for cancelled claims 1-15.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

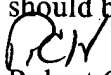
Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

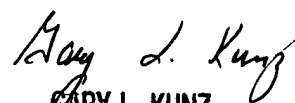
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Robert C. Hayes, Ph.D.
July 1, 2002


GARY L. KUNZ
SUPERVISORY PATENT EXAMINER
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